

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

11 STEVE SHIELDS

12 Plaintiff,

13 v. No. C15-2580 CRB
ORDER GRANTING MOTION TO
DISMISS14 ALERE HOME MONITORING, INC.,
15 ALERE SAN DIEGO, INC.16 Defendants.
17 _____/

18 Plaintiff Steve Shields filed this putative class action against Defendants Alere Home
19 Monitoring, Inc. and Alere San Diego, Inc. (collectively, “Alere”), alleging fraudulent and
20 unfair business practices in connection with Alere’s sale of INRatio PT/INR Monitoring
21 Systems (collectively, the “INRatio Systems” or the “devices”). Alere now moves to dismiss
22 Shields’s complaint for failure to state a claim under California’s Consumer Legal Remedies
23 Act (“CLRA”) and under California’s Unfair Competition Law (“CUCL”). For the reasons
24 set forth below, the Court GRANTS Alere’s motion to dismiss.

25 **I. BACKGROUND**

26 **A. The INRatio Systems**

27 The INRatio Systems are Class II medical devices used by healthcare professionals or
28 patients at home to monitor the anticoagulation effects of blood thinning medications. See
First Amended Complaint (“FAC”) (dkt. 10) ¶ 1; Request for Judicial Notice (“Request”)
(dkt. 22), Ex. A (FDA INRatio 501(k) Substantial Equivalence Determination Decision

1 Summary, § H, Intended Use) at 1–2. Patients can only obtain these devices with a
2 prescription. See id. § B (Purpose for Submission) at 1. The devices permit patients to
3 monitor their blood at home, rather than having to have blood drawn at a lab on a weekly or
4 monthly basis. See id.; FAC ¶ 1. The INRatio Systems consist of an electronic monitor for
5 interpreting test strips as well as test strips onto which patients place a blood sample. See
6 FAC ¶ 1.

7 The package insert for the INRatio Systems provides instructions on its use and a
8 number of warnings about circumstances in which the devices can yield inaccurate results.
9 See generally Request, Ex. B (INRatio2 Self Test User Guide). For example, the INRatio2
10 user guide states:

11 **Your current health status**

12 Current health status may affect test results and cause inaccurate results or
13 results that are not what you expect. It's important to take certain health factors
14 into consideration when interpreting test results and deciding on a course of
15 action with your health care provider. Failure to do so may lead to an incorrect
16 interpretation of the PT monitor results.

17 Id. at 8; see also id. at 7–8 (listing a series of precautions and limitations on use of the
18 device).

19 **B. Alere's Correction Letter and the FDA's Recall of INRatio Systems**

20 On December 4, 2014, Alere released an urgent “Medical Device Correction,” (the
21 “correction letter”) in which it advised patients that, under certain circumstances, the INRatio
22 Systems could yield inaccurate results. See Request, Ex. C (Urgent Medical Device
23 Correction) at 1. That same day, the U.S. Food and Drug Administration (“FDA”) issued a
24 Class I recall¹ of the devices and test strips because the FDA found that they may provide a
25 test result lower than the expected result obtained using a laboratory method. Id., Ex. E
26 (FDA Recall Notice) at 2. In its notice, the FDA informed device users that Alere had

27 ¹ The FDA defines the term “recall” broadly to include both “removal” and “correction” of a
28 marketed product. See Request for Judicial Notice, Ex. D (FDA Recalls, Corrections and Removals
 (Devices)) at 2. A “correction” does not require the removal of a product from the market, but rather
 requires the “repair, modification, adjustment, relabeling, destruction, or inspection . . . of a product
 without its physical removal to some other location.” Id.

1 received 18,924 complaints about the INRatio Test Strips from 2013–2014, though “not all
2 of [the complaints] are related to the recall.” See id.

3 Both Alere’s correction letter and the FDA recall notice advised patients that incorrect
4 results could occur if a patient had certain medical conditions such as anemia, conditions
5 associated with elevated fibrinogen levels, or unusual bleeding or bruising. See Urgent
6 Medical Device Correction at 1; FDA Recall Notice at 1. Specifically, Alere advised
7 INRatio Systems users:

8 **You should contact your doctor to determine if any of these medical conditions
9 apply to you:**

- Anemia (low hemoglobin or low red blood cell count). Your hematocrit should be between 30 – 50%
- Any conditions associated with elevated fibrinogen levels (Note: fibrinogen is the protein from which a clot is formed)
 - acute inflammatory conditions (for example viral or bacterial infections such as pneumonia or flu)
 - chronic inflammatory conditions (for example rheumatoid arthritis, Crohn’s disease, ulcerative colitis, infectious liver diseases such as hepatitis, or inflammatory kidney diseases such as diabetic nephropathy and glomerulonephritis)
 - severe infection (for example sepsis)
 - advanced stage cancer or end stage renal disease requiring hemodialysis
- any bleeding or unusual bruising

16 See Urgent Medical Device Correction at 1 (emphasis in original). Alere and the FDA
17 instructed patients to discuss with their doctors whether any of the above medical conditions
18 applied to them, and if so, they recommended certain procedures. See Urgent Medical
19 Device Correction at 1; FDA Recall Notice at 2.

20 Neither Alere’s correction letter nor the FDA’s recall notice directed all patients to
21 cease use of the devices. See Urgent Medical Device Correction at 1–2; FDA Recall Notice
22 at 1–2. Only those patients with the conditions “detailed in the correction letter” were
23 advised to stop using the INRatio Systems. See FDA Recall Notice at 2. The FDA has not
24 mandated removal of the INRatio Systems from the medical device field—the devices
25 remain on the market. See Guerdan Decl. (dkt. 21-1) ¶¶ 4, 8. See generally FDA Recall
26 Notice. Alere, with FDA oversight, currently is working to upgrade the INRatio Systems
27 software to reduce the potential for inaccurate test results. See Guerdan Decl. ¶ 6.

1 **C. Shields's First Amended Complaint**

2 Shields seeks to represent a national class of persons who paid for the INRatio
3 Systems as well as a national subclass of persons who bought the device for "personal use,"
4 as defined by the California Consumer Legal Remedies Act ("CLRA"), Cal. Civ. Code
5 § 1750, et seq. See FAC ¶¶ 24–25.

6 Shields asserts that he purchased an INRatio device "[o]n or about [] 2012" to monitor
7 his blood. See FAC ¶ 21. After purchasing the device, Shields purchased "numerous \$20
8 'test strips.'" Id. Shields states that he decided to purchase the device "based on
9 promotional materials he saw on the internet." See id. According to Shields, Alere engaged
10 in an "aggressive marketing campaign" that was directed at consumers and physicians. See
11 id. ¶ 13. Throughout the class period, Shields states, Alere's "website, product manual, and
12 promotional materials" promoted the INRatio Systems's "simplicity, accuracy, and
13 convenience." See id. Shields explains that he was "told and relied upon the statements"
14 that the device was "accurate and reliable" and a "convenient alternative to traditional lab
15 tests." See id. ¶ 21.

16 Shields alleges that shortly after the INRatio Systems hit the market, Alere "began
17 receiving reports" that the Systems were not providing accurate readings. See id. ¶ 14.
18 According to Shields, an FDA inspection of Alere's San Jose manufacturing facility revealed
19 that by October 2005, Alere knew their Systems were producing erroneous results. See id.
20 The FDA's October 4, 2005 Warning Letter stated that "[The FDA's] review indicates that
21 your firm had information indicating that INRatio devices were generating clinically
22 significant erroneous values." See id. ¶ 15. Shields alleges that this statement by the FDA
23 implies that Alere was "trying to conceal" the devices' problems from the FDA. See id.

24 Shields alleges that he recently learned that his INRatio device "was not reliable and
25 was not a convenient alternative to traditional lab tests." See id. ¶ 22. Shields argues that he
26 is now the owner of an INRatio device that is "essentially worthless." Id. Shields thus
27 brings two causes of action. First, Shields alleges that Alere employed unfair or deceptive
28 business practices intended to result in the sale of the INRatio Systems in violation of the

1 CLRA. See FAC ¶¶ 1, 13, 37. Shields argues that Alere's acts and practices violated, and
2 continue to violate, the CLRA in three respects: (1) Alere represents that the INRatio
3 Systems have characteristics, uses, or benefits that they do not have; (2) Alere represents that
4 the INRatio Systems "are of a particular standard, quality, or grade when they are of
5 another"; and (3) Alere advertises goods with the intent not to sell them as advertised. See
6 id. ¶ 37.

7 Second, Shields alleges that, under the CUCL, Alere "knew their INRatio system was
8 unreliable, inaccurate, and not suitable substitute [sic] for traditional laboratory tests." See
9 id. ¶ 43. Shields further alleges that Alere "knowingly misrepresented the reliability of" the
10 INRatio Systems. See id. ¶ 45. Finally, Shields alleges that Alere knowingly sold and
11 continues to sell the INRatio Systems "while concealing and suppressing the nature and
12 scope of the problems" with these devices. See id. ¶ 44.

13 Shields now seeks the following remedies from this Court: (1) compensatory damages
14 to be determined at trial; (2) a civil penalty against Alere pursuant to California Civil Code
15 § 1794; (3) restitution of funds "unlawfully acquired" by Alere by means of any acts or
16 practices in violation of the CUCL; (4) an injunction to prohibit Alere from engaging in the
17 unfair business practices described in the complaint; (5) punitive damages; (6) attorneys'
18 fees; (7) costs and expenses; and (8) any other relief deemed just and proper by this Court.
19 See FAC, Prayer for Relief ¶¶ 1–8.

20 **D. Summary of Alere's Arguments Presented in the Motion to Dismiss**

21 Alere contends that Shields's FAC should be dismissed for two reasons: First, Shields
22 lacks Article III standing to bring his claims because (1) Shields has not alleged an injury in
23 fact and (2) nothing suggests that Shields was using an INRatio Systems device at the time
24 that Alere's correction letter was issued. See Mot. to Dismiss (dkt. 21) at 4–8. Thus, Alere
25 asserts, Shields's complaint should be dismissed pursuant to Federal Rule of Civil Procedure
26 12(b)(1). See id. Second, Alere argues that Shields fails to state a claim upon which relief
27 can be granted because (1) Shields has not alleged facts to support a CLRA violation based
28 on affirmative misrepresentation and (2) Shields has failed to satisfy the "unlawful,"

1 “unfair,” and “fraudulent” prongs of the CUCL. See id. at 8–13. Accordingly, Alere asserts
2 that Shields’s complaint should be dismissed pursuant to Federal Rule of Civil Procedure
3 12(b)(6). See id.

4 **II. LEGAL STANDARD**

5 **A. Federal Rule of Civil Procedure 12(b)(1)**

6 A plaintiff must “have ‘standing’ to challenge the action sought to be adjudicated in
7 the lawsuit.” Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc., 454 U.S. 464, 471 (1982). To establish Article III standing, a plaintiff must satisfy three
9 “irreducible constitutional minimum” requirements: (1) he suffered an “injury in fact,”
10 meaning a concrete and particularized injury that is actual or imminent; (2) the injury must
11 be causally related to the defendant’s challenged actions; and (3) it must be “likely” that the
12 injury will be “redressed by a favorable court decision.” Lujan v. Defenders of Wildlife, 504
13 U.S. 555, 560–61 (1992). The plaintiff, as the party invoking federal jurisdiction, has the
14 burden of establishing these elements. Id. at 561.

15 Article III standing implicates the court’s subject matter jurisdiction, and is thus
16 subject to challenge under Federal Rule of Civil Procedure 12(b)(1). See Maya v. Centex Corp., 658 F.3d 1060, 1067 (9th Cir. 2011). Rule 12(b)(1) attacks can be either facial,
18 confining the inquiry to allegations in the complaint, or factual, permitting the court to look
19 beyond that complaint. White v. Lee, 227 F.3d 1214, 1242 (9th Cir. 2000). Once the
20 moving party has converted the motion to dismiss into a factual motion by presenting
21 evidence demonstrating a lack of subject matter jurisdiction, the opposing party must furnish
22 evidence necessary to satisfy its burden of establishing that the court, in fact, possesses
23 subject matter jurisdiction. Savage v. Glendale Union High Sch., Dist. No. 205, Maricopa Cty., 343 F.3d 1036, 1039 n.2 (9th Cir. 2003) (considering affidavits furnished by both
25 parties in evaluating Rule 12(b)(1) motion to dismiss); St. Clair v. City of Chico, 880 F.2d
26 199, 201 (9th Cir. 1989) (“Unlike a Rule 12(b)(6) motion, a Rule 12(b)(1) motion can attack
27 the substance of a complaint’s jurisdictional allegations despite their formal sufficiency, and
28 in so doing rely on affidavits or any other evidence properly before the court.”).

B. Federal Rule of Civil Procedure 12(b)(6)

A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) tests whether the complaint “contain[s] sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). When deciding a Rule 12(b)(6) motion, the court must accept the facts pleaded in the complaint as true, and construe them in the light most favorable to the plaintiff. Falkner v. ADT Sec. Servs. Inc., 706 F.3d 1017, 1019 (9th Cir. 2013); Cousins v. Lockyer, 568 F.3d 1063, 1067–68 (9th Cir. 2009). The court, however, is not required to accept “legal conclusions . . . cast in the form of factual allegations.” W. Mining Council v. Watt, 643 F.2d 618, 624 (9th Cir. 1981); see Iqbal, 556 U.S. at 678; Twombly, 550 U.S. at 555.

After accepting all non-conclusory allegations as true and drawing all reasonable inferences in favor of the plaintiff, the court must determine whether the complaint alleges a plausible claim to relief. See Iqbal, 556 U.S. at 679–80. A claim is plausible on its face when the plaintiff “pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Id. at 678.

C. Federal Rule of Civil Procedure 9(b)

Allegations of fraud and allegations that “sound in fraud” must be pleaded with particularity. Fed. R. Civ. P. 9(b); Vess v. Ciba-Geigy Corp. U.S.A., 317 F.3d 1097, 1103–05 (9th Cir. 2003). Conclusory allegations of fraud are insufficient. Moore v. Kayport Package Express, Inc., 885 F.2d 531, 540 (9th Cir. 1989). A pleading satisfies Rule 9(b) when it is “specific enough to give defendants notice of the particular misconduct . . . so that they can defend against the charge and not just deny that they have done anything wrong.” Vess, 317 F.3d at 1106. Consequently, a plaintiff must plead “the who, what, when, where, and how” of the alleged fraud. Id. A plaintiff must therefore “state the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations.” Schreiber Distrib. Co. v. Serv-Well Furniture Co., 806 F.2d 1393, 1401 (9th Cir. 1986). Further, if the plaintiff claims that a statement is false or misleading, “[t]he

1 plaintiff must set forth what is false or misleading about a statement, and why it is false.” In
 2 re GlenFed, Inc. Sec. Litig., 42 F.3d 1541, 1548 (9th Cir. 1994) (emphasis added).²

3 **III. DISCUSSION**

4 **A. Shields Lacks Article III Standing**

5 Alere moves to dismiss the FAC for lack of Article III standing, offering the following
 6 two arguments: (1) Shields has not alleged an injury in fact and (2) Shields did not use the
 7 INRatio Systems during the relevant time period, which is required to sufficiently allege
 8 injury in fact. See Mot. to Dismiss at 4–8. Shields responds that his injuries are “purely
 9 economic” and that he is entitled to relief because his device is “worthless” given that it does
 10 not reliably provide accurate results. See Opp. at 7.

11 **1. Shields has not alleged an injury to himself**

12 Shields does not claim that he has suffered or imminently will suffer from relying on
 13 an inaccurate INRatio test result. Shields fails to even allege that he has received an
 14 inaccurate test result himself or that he imminently will receive one. If Shields had alleged
 15 that he suffered from one of the medical conditions detailed in Alere’s correction letter, his
 16 imminent risk of receiving an inaccurate and detrimental test result might have been
 17 cognizable. Shields fails to include those allegations in the FAC. Instead, he sweepingly
 18 argues that because the INRatio Systems may produce inaccurate results in some situations,
 19 those possible inaccuracies render the entire device unreliable and inaccurate.

20 See FAC ¶ 22; Opp. at 4.

21 Shields thus fails to allege that he personally suffered a concrete and particularized
 22 injury. See Lujan, 504 U.S. at 561 n.1 (“By particularized, we mean that the injury must
 23 affect the plaintiff in a personal and individual way.”); Warth v. Seldin, 422 U.S. 490, 501
 24 (“[T]he plaintiff still must allege a distinct and palpable injury to himself, even if it is an

25
 26 ² A motion to dismiss a claim or complaint “grounded in fraud” under Rule 9(b) for failure
 27 to plead with particularity is the “functional equivalent” of motion to dismiss under Rule 12(b)(6)
 28 for failure to state a claim. Vess, 317 F.3d at 1107. “If insufficiently pled averments of fraud are
 disregarded, as they must be, in a complaint or claim grounded in fraud, there is effectively nothing
 left in the complaint.” Id. Given that dismissal of a complaint or claim has the same consequences
 under both Rule 9(b) and Rule 12(b)(6), dismissals under the two rules are treated in the same
 manner. Id.

1 injury shared by a large class of other possible litigants.”) (emphasis added). At most,
2 Shields pleads a potential risk of inaccurate test results that could affect other, unidentified
3 INRatio Systems users who disregard Alere’s warnings and use the devices even though they
4 suffer from one of the few at-risk medical conditions detailed in Alere’s correction letter.
5 Shields’s claim thus fails because he has not alleged a sufficient injury “to himself” and
6 therefore lacks standing. See Seldin, 422 U.S. at 501; Cal. Bus. & Prof. Code §§
7 17203–17204 (authorizing representative CUCL claims on behalf of others only if the
8 claimant meets standing requirements, including injury in fact).

9 2. Shields’s injury is hypothetical and alleged economic harm here does
10 not constitute injury in fact

11 Shields responds that his alleged injury—possessing a “worthless” device—is not
12 hypothetical because “there have been more than 18,000 complaints that the device does not
13 provide accurate results.” See FAC ¶ 17; Opp. at 6. Shields reasons that these complaints
14 prove the INRatio Systems do not provide accurate results, are unreliable, and are
15 “essentially worthless for all purchasers.” See FAC ¶ 19; Opp. at 6. Shields further argues
16 that the FDA recall notice supports his “core allegation that the monitor does not work as
17 intended.” See Opp. at 6. Shields reasons that his injury is not hypothetical because he “in
18 fact . . . purchased a home monitoring device that is now completely useless.” See Opp. at 7.
19 Shields alleges that owning a worthless medical device that “he paid hundreds of dollars for”
20 constitutes an actual, non-hypothetical injury. See *id.*

21 Furthermore, Shields claims that the INRatio Systems’s inherent potential to produce
22 inaccurate test results for some individuals with certain medical conditions has reduced the
23 value of his device. See FAC ¶ 19; Opp. at 6. Specifically, Shields argues that because the
24 INRatio Systems might produce inaccurate results for a subset of users, the devices are
25 “worthless,” and “[paying] hundreds of dollars” for a “worthless product” amounts to injury
26 in fact under Article III. See Opp. at 6–7.

27 The Court concludes, however, that Shields has failed to allege anything more than
28 the possibility that he could have suffered harm; his arguments about economic injury fail
under Ninth Circuit case law. In Birdsong v. Apple, Inc., a case in which the plaintiffs

1 alleged economic harm given that a product defect had allegedly lowered the value of their
2 iPods, the Ninth Circuit held that the plaintiffs' alleged economic injury was not an injury in
3 fact. 590 F.3d 955 (9th Cir. 2009). In that case, plaintiffs failed to claim that they used their
4 iPods in a way that exposed them to the alleged injury, hearing loss. Id. at 960. At most, the
5 plaintiffs alleged a potential risk of hearing loss not to themselves, but to other unidentified
6 iPod users who might choose to use their iPods in an unsafe manner. Id. (emphasis in
7 original). The court therefore concluded that the alleged loss in value of the iPods did not
8 constitute "distinct and palpable injury that is actual or imminent" because it rested on the
9 "hypothetical risk" of injury to other consumers "who may or may not choose to use" their
10 products in a risky manner. Id. at 961.

11 Here, as in Birdsong, Shields's allegation of suffering a "purely economic" injury, see
12 Opp. at 7, rests entirely on a risk of harm to other consumers, and even then, a harm that
13 might only occur if those consumers fall within the at-risk category and ignore the
14 instructions of Alere's correction letter. See 590 F.3d at 961; Urgent Medical Device
15 Correction at 1. Shields's FAC establishes only a "hypothetical" risk of harm that is
16 insufficient to establish injury in fact as required by Article III. See id.; Lujan, 504 U.S. at
17 561 n.1. The Court thus concludes that the FAC should be dismissed. See
18 Fed. R. Civ. P. 12(b)(1).

19 **B. The FAC Fails Generally Under Rule 9(b)**

20 Shields alleges that Alere fraudulently misrepresented information about the INRatio
21 Systems and concealed knowledge of product defects. See FAC ¶¶ 1, 2, 37–38, 40, 43–46.
22 A plaintiff alleging fraudulent conduct must satisfy Rule 9(b)'s heightened pleading
23 standard, which requires the plaintiff to plead the circumstances constituting fraud with
24 particularity. Kearns v. Ford Motor Co., 567 F.3d 1120, 1126 (9th Cir. 2009).

25 Shields generally pleads that he relied upon Alere's statements that the devices were
26 accurate and reliable. See FAC ¶ 21 ("The reason [Shields] decided to purchase the System
27 was based on promotional materials he saw on the internet. Specifically, Plaintiff was told
28 and relied upon the statements that the System was accurate and reliable. . . ."). Rule 9(b)'s

1 particularity requirement can be satisfied by “identifying or attaching the representative
2 samples” if the alleged misrepresentations occur in printed form. See, e.g., Von Koeing v.
3 Snapple Beverage Corp., 713 F. Supp. 2d 1066, 1078 (E.D. Cal. 2010) (dismissing plaintiff’s
4 claims to the extent that they were “based upon other advertisements and marketing or based
5 upon other labels not submitted to the court.”); Ries v. Hornell Brewing Co., Inc., 2011 WL
6 1299286 at *4 (N.D. Cal. April 4, 2011) (same).

7 Shields fails to adequately identify or attach representative samples here. In Kearns v.
8 Ford Motor Co., a case in which the plaintiff’s complaint failed to identify what
9 advertisements or sales materials he had relied upon when purchasing a product, the Ninth
10 Circuit affirmed the dismissal of the plaintiff’s complaint under Rule 9(b). See 567 F.3d at
11 1126. The court held the plaintiff’s allegations insufficient, where the plaintiff failed to
12 specify “what the television advertisements or sales material stated [or] when he was exposed
13 to them or which ones he found material.” Id. at 1125–26. Shields, like the plaintiff in
14 Kearns, fails to indicate what particular statements (in advertisements or otherwise) he relied
15 upon when purchasing his INRatio device. See 567 F.3d at 1125–26. Shields does not allege
16 who specifically stated that the INRatio Systems were “accurate and reliable,” nor does he
17 state where or when he saw or heard that representation. See Minkler v. Apple, Inc.,
18 65 F. Supp. 3d 810, 821 (N.D. Cal. 2014) (holding insufficient allegations “that Apple made
19 specific representations that [its] Maps [application] would be accurate and improve over
20 time” because plaintiff failed to identify “any specific statement by Apple that expressly
21 indicates that Apple Maps would always work flawlessly and without error”). As a result,
22 Shields’s claims fail under Rule 9(b). See Kearns, 567 F.3d at 1125–26.

23 C. Shields Fails to Adequately Plead a CLRA Claim

24 The CLRA prohibits “unfair methods of competition and unfair or deceptive acts or
25 practices” in consumer sales. Cal. Civ. Code § 1770; Berger v. Home Depot USA, Inc., 741
26 F.3d 1061, 1069 (9th Cir. 2014). A consumer may bring an action under the CLRA pursuant
27 to § 1780(a), which provides that “[any] consumer who suffers any damage as a result of the
28

1 use or employment by any person of a method, act, or practice declared to be unlawful by
2 Section 1770 may bring an action against that person . . .” Cal. Civ. Code § 1780(a).

3 Shields argues that Alere violated the CLRA by: (1) representing that the INRatio
4 Systems have “characteristics, uses or benefits they do not have”; (2) representing that the
5 devices “are of a particular standard, quality or grade when they are of another”; and (3)
6 advertising the devices with intent not to sell them as advertised. See FAC ¶ 37.

7 1. Injury

8 The CLRA allows recovery when a consumer “suffers any damage as a result of” the
9 unlawful practice. Cal. Civ. Code § 1780(a). This provision “requires that plaintiffs in a
10 CLRA action show not only that a defendant’s conduct was deceptive but that the deception
11 caused them harm.” In re Vioxx Class Cases, 180 Cal. App. 4th 116, 129 (Ct. App. 2009);
12 see also Berger, 741 F.3d at 169 (“[T]he CLRA demands that each potential class member
13 have both an actual injury and show that the injury was caused by the challenged practice.”).
14 The meaning of “any damage” is not defined in the CLRA. In enacting the CLRA, the
15 legislature “set a low but nonetheless palpable threshold of damage.” Meyer v. Sprint
16 Spectrum L.P., 45 Cal. App. 4th 634, 646 (Ct. App. 2009). California courts have thus
17 recognized that “damage” under the CLRA is not synonymous with “actual damages,” and
18 may encompass “harms other than pecuniary damages.” In re Steroid Hormone Prod. Cases,
19 181 Cal. App. 4th 145, 156 (Ct. App. 2010). A consumer may allege harm from having
20 purchased an item that he would not have bought but for defendant’s deceptive marketing
21 practices. Id.

22 Here, Shields has failed to adequately plead that he has suffered damages as a result of
23 any representation made by Alere. As discussed above, Shields has not alleged that he has
24 received an inaccurate result from his INRatio device. See Birdsong, 590 F.3d at 961
25 (holding that a hypothetical risk of harm is insufficient to establish injury in fact);
26 Seldin, 422 U.S. at 501 (requiring a plaintiff to allege a distinct and palpable injury to
27 himself) (emphasis added). Moreover, Shields has failed to sufficiently allege that Alere’s
28 conduct was deceptive. Shields claims that Alere’s materials were deceptive because they

1 stated that the INRatio Systems were “accurate and reliable,” when they were not. See FAC
2 ¶¶ 13–14. Yet, Shields provides no description of these materials upon which he allegedly
3 relied, nor does he point to any specific material for the Court to evaluate for deceptiveness.
4 See Vess, 317 F.3d at 1106 (requiring a plaintiff to plead “the who, what, when, where, and
5 how” of the alleged fraud); In re Sony Gaming Networks & Customer Data Sec. Breach
6 Litig., 996 F. Supp. 2d 942, 989 (S.D. Cal. 2014) (explaining that the determination of
7 deceptive or misleading conduct is “fact intensive”). The only material Shields points to
8 with sufficiency is Alere’s correction letter, which provides transparent, non-deceptive
9 caveats regarding the accuracy and reliability of the INRatio Systems. See Urgent Medical
10 Device Correction at 1 (advising patients that, under certain circumstances, the INRatio
11 Systems could yield inaccurate results).

12 2. Particularity

13 Alere contends that Shields’s CLRA claim is based upon misrepresentations and
14 fraudulent omissions and thus must meet the heightened pleading requirements applicable to
15 fraud-based claims. See Mot. to Dismiss at 9. Federal Rule of Civil Procedure 9(b) applies
16 to claims brought under the CLRA and CUCL where a “unified course of fraudulent
17 conduct” is alleged as the basis of such a claim. Kearns, 567 F.3d at 1125. Here, Shields
18 alleges that Alere violated the CLRA by misrepresenting the reliability and accuracy of its
19 INRatio Systems. See FAC ¶ 37. Given that Shields’s CLRA claim relies on a course of
20 allegedly deceptive conduct by Alere, the requirements of Rule 9(b) apply. See Kearns, 567
21 F.3d at 1125.

22 Shields has not adequately pled—under Rule 9(b)—that Alere misrepresented the
23 reliability and accuracy of the INRatio Systems. In Doe 1 v. AOL LLC, a case in which the
24 plaintiffs specified misleading statements made by AOL in its privacy policy and other
25 statements posted on AOL’s website, the court held that the plaintiffs had alleged sufficient
26 facts to satisfy Rule 9(b)’s heightened pleading requirements. 719 F. Supp. 2d 1102, 1112
27 (N.D. Cal. 2010). In that case, AOL represented to its consumers that AOL would endeavor
28 to maintain the privacy and security of their personal information. Id. The plaintiffs alleged,

1 however, that AOL later made confidential data pertaining to 658,000 AOL members
2 available to the public. Id. The court found that such allegations were sufficient to satisfy
3 the purpose of Rule 9(b), which “is to ensure that defendants accused of the conduct
4 specified have adequate notice of what they are alleged to have done, so that they may
5 defend against the accusations.” Id.; Concha v. London, 62 F.3d 1493, 1502 (9th Cir. 1995).

6 Here—unlike in Doe 1, where plaintiffs alleged that AOL represented to its customers
7 that their information would remain private but subsequently made the information available
8 to the public—Shields has not adequately alleged that Alere misrepresented the reliability
9 and accuracy of the INRatio Systems. See 719 F. Supp. 2d at 1112. Shields simply asserts
10 that Alere received 18,924 complaints “related to the [INRatio] System[s].” See FAC ¶ 2.
11 Shields does not allege that these complaints stated that the INRatio Systems produced
12 inaccurate or unreliable results, nor does Shields allege that he himself received inaccurate or
13 unreliable results from his INRatio device. Further, Shields fails to adequately identify the
14 alleged deceptive materials. See Vess, 317 F.3d at 1106 (requiring a plaintiff to “state the
15 time, place, and specific content of the false representations as well as the identities of the
16 parties to the misrepresentations”). Shields merely claims that the deceptive materials
17 consisted of “Alere’s website, product manual, and promotional materials,” as well as
18 “promotional materials he saw on the internet.” See FAC ¶¶ 13, 21. The Court thus
19 concludes that Shields’s CLRA claim fails under Rule 9(b)’s particularity requirement. See
20 Doe 1, 719 F. Supp. 2d at 1112.

21 3. Causation

22 Under the CLRA, a claim may be brought by a consumer who has suffered injury “as
23 a result of the use or employment of a proscribed method, act, or practice.” Cal. Civ. Code §
24 1780(a) (emphasis added). For purposes of the CLRA, causation is sufficiently alleged
25 where the complaint plausibly suggests that the defendant’s misrepresentation “played a
26 substantial part, and so has been a substantial factor” in influencing the plaintiff’s actions,
27 which, in turn, led to his harm. Hale v. Sharp Healthcare, 183 Cal. App. 4th 1373, 1386–87
28 (Ct. App. 2010). For example, allegations that the plaintiff entered into an agreement

1 expecting that “regular” rates would be charged instead of the excessive rates actually
2 charged have been sufficient to plead causation under the CLRA and CUCL. See id.

3 In Doe 1, where plaintiffs alleged that AOL misrepresented that it would protect
4 members’ private information from public disclosure, the court held that plaintiffs adequately
5 demonstrated a link between their reliance on AOL’s misrepresentations and their injury.
6 719 F. Supp. 2d at 1113. The court explained that a reasonable consumer would have serious
7 reservations about disclosing sensitive, personal data if she or he were aware that AOL,
8 contrary to its privacy policy, would make such information readily available to the public
9 without consumers’ knowledge or consent. Id. For this reason the court found that plaintiffs
10 had adequately alleged causation for purposes of stating a claim under the CLRA. Here,
11 unlike in Doe 1, Shields cannot establish the requisite link between Alere’s alleged
12 misrepresentations and his injury because he has not established an injury in the first place.
13 See Birdsong, 590 F.3d at 961; Lujan, 504 U.S. at 561 n.1. The Court therefore concludes
14 that Shields has failed to satisfy the CLRA’s causation requirement. See Cal. Civ. Code §
15 1780(a).

16 **D. Shields Fails to Adequately Plead a CUCL Claim**

17 The CUCL prohibits unfair competition, which it broadly defines as including “any
18 unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or
19 misleading advertising.” Cal. Bus. & Prof. Code § 17200; Kearns, 567 F.3d at 1126. Each
20 prong of the CUCL is a separate and distinct theory of liability. Kearns, 567 F.3d at 1126.
21 Under the CUCL, a private enforcement action can only be brought by “a person who has
22 suffered injury in fact and has lost money or property as a result of the unfair competition.”
23 § 17204; Kwikset v. Superior Court, 51 Cal. 4th 310, 321–22 (Cal. 2011); In re Tobacco II
24 Cases, 46 Cal. 4th 298, 324–25 (Cal. 2009). Moreover, if a CUCL claim is said to be
25 grounded in fraud, “the pleading of that claim as a whole must satisfy the particularity
26 requirement of [FRCP] Rule 9(b).” Kearns, 567 F.3d at 1126 (quoting Vess, 317 F.3d at
27 1103–04).

28

1 1. The “unlawful” prong of the CUCL

2 The CUCL prohibits “unlawful” practices. Saunders v. Superior Court, 27 Cal. App.
3 4th 832, 838 (Ct. App. 1994). The statute “borrows” violations of other laws and treats them
4 as actionable. Cel-Tech Commc’ns v. Los Angeles Cellular Tel. Co., 20 Cal. 4th 163, 180
5 (Ct. App. 1999).

6 In his FAC, Shields makes only a cursory suggestion that Alere engaged in
7 “unlawful” practices. See FAC ¶ 47 (“Defendants’ unlawful and unfair business practices
8 present a continuing and ongoing threat to the public in that Defendants continue to mislead
9 and deceive the public regarding the quality and nature of the INRatio Systems.”). Shields
10 does not identify any specific statute or law that Alere allegedly violated. In his opposition,
11 Shields argues that the FAC establishes “unlawful” conduct by citing the Federal Food,
12 Drug, & Cosmetic Act (“FDCA”), which requires medical device manufacturers to provide
13 adequate warnings and refrain from falsely advertising the benefits of their devices. See 21
14 U.S.C. § 352(a); Opp. at 11. Shields also alleges a violation of the CLRA. See Opp. at 11.

15 As Alere highlights, however, Shields’s FAC never mentions a violation of the
16 FDCA. See Mot. to Dismiss at 6. Moreover, Shields has not pled facts showing that Alere’s
17 corrective action or the FDA recall has any relevance to him; he has not alleged that he
18 suffers from any of the medical conditions at issue in the correction and recall. Shields,
19 given his medical condition, thus cannot claim that his INRatio device provides him readings
20 less accurate than it was advertised to provide at the time of sale. On the contrary, Shields
21 effectively asks this Court to adopt a rule that any time a drug or device manufacturer issues
22 a new warning, all previous purchasers should get their money back, regardless of whether
23 the new warning has any application to them. See Mot. to Dismiss at 6. The Court declines
24 this invitation.

25 2. The “unfair” prong of the CUCL

26 Under California law, an act or practice is “unfair” if the consumer injury is
27 “substantial, is not outweighed by any countervailing benefits to consumers or to
28 competition, and is not an injury the consumers themselves could reasonably have avoided.”

1 Daugherty v. Am. Honda Motor Co., Inc., 144 Cal. App. 4th 824, 839 (Ct. App. 2006). As
2 discussed above, Shields has not adequately pled injury from using his INRatio device, and
3 the Court therefore concludes that Shields has failed to satisfy the “unfair” prong of the
4 CUCL.

5 3. The “fraudulent” prong of the CUCL

6 To satisfy the CUCL “fraudulent” prong, a plaintiff must allege that the defendant
7 acted in a way likely to deceive a reasonable consumer. Clemens v. DaimlerChrysler Corp.,
8 534 F.3d 1017, 1125 (9th Cir. 2008). Here, Shields fails to satisfy the CUCL’s “fraudulent”
9 prong for three reasons. First, Shields alleges that Alere deceived consumers, including
10 Shields, into purchasing “unreliable” INRatio Systems. See FAC ¶ 44. As discussed above,
11 however, Shields fails to identify with particularity any false or deceptive statements he
12 personally saw or upon which he actually relied—as is required when a CUCL claim, like
13 Shields’s, is grounded in fraud. See Kearns, 567 F.3d at 1126; Minkler v. Apple, Inc., 65 F.
14 Supp. 3d at 821; see also In re Tobacco II Cases, 46 Cal. 4th at 326 (a private person
15 asserting a CUCL claim must demonstrate actual reliance on allegedly misleading
16 statements); Laster v. T-Mobile USA, Inc., 407 F. Supp. 2d 1181, 1194 (S.D. Cal. 2005),
17 aff’d, 252 F. App’x 777 (9th Cir. 2007).

18 Second, the alleged fraudulent statements that Shields proffers amount to nothing
19 more than non-actionable puffery. Shields alleges that Alere promoted the INRatio
20 Systems’s “simplicity, accuracy, and convenience,” and represented that the devices were
21 “accurate and reliable” and a “convenient alternative to traditional lab tests.” See FAC ¶ 21.
22 Although “[m]isdescriptions of specific or absolute characteristics of a product are
23 actionable,” Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1145 (9th Cir. 1997)
24 (citation omitted), “[g]eneralized, vague, and unspecified assertions, constitute ‘mere
25 puffery’ upon which a reasonable consumer could not rely, and hence are not actionable,”
26 Anunziato v. eMachines, Inc., 402 F. Supp. 2d 1133, 1139 (C.D. Cal. 2005) (quoting Glen
27 Holly Entm’t, Inc. v. Tektronix Inc., 343 F.3d 1000, 1015 (9th Cir. 2003)). Here, the
28 allegedly fraudulent terms used by Alere are general assertions that say nothing about the

1 specific characteristics or components of the INRatio Systems and provide nothing concrete
2 upon which a reasonable consumer could rely. See Anunziato v. eMachines, Inc., 402 F.
3 Supp. 2d at 1140–41 (holding that such terms as “reliable,” “high quality,” “high
4 performance,” and “latest technology” are non-actionable puffery); see also Shroyer v. New
5 Cingular Wireless Servs., Inc., 622 F.3d 1035, 1042–43 (9th Cir. 2010) (holding that
6 “advantages” is too vague); cf. Cook, Perkiss & Liehe, Inc., 911 F.2d 242, 246 (9th Cir.
7 1990) (holding that advertiser’s statement that its lamps were “far brighter than any lamp
8 ever before offered for home movies” was puffery; however, when the advertiser quantified
9 numerically the alleged superior brightness with statements such as “35,000 candle power
10 and 10-hour life,” the assertions became actionable) (citation omitted)).

11 Third, Shields has failed to allege how any omission of relevant information has
12 harmed him. Shields has not pled that he possesses one of the at-risk medical conditions
13 detailed in Alere’s correction letter, nor has he pled any facts suggesting that he obtained his
14 device with a prescription and that Alere’s representations deceived his prescribing doctor.
15 Shields has thus failed to satisfy the “fraudulent” prong of the CUCL. See In re Tobacco II
16 Cases, 46 Cal. 4th at 326.

17 **V. CONCLUSION**

18 For the foregoing reasons, this Court GRANTS Alere’s motion to dismiss.

19 **IT IS SO ORDERED.**

20
21 Dated: November 17, 2015



CHARLES R. BREYER
UNITED STATES DISTRICT JUDGE

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